FDA 510(k) Premarket Notification

K203421 Triathlon AS-1

CLEARED

Apr 19, 2021
150 days to decision

K203421 · Product code: **OOG** · Orthopedic
Source: https://www.510kdatabase.net/k203421/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Knee Arthroplasty Implantation System (OOG)
Date received	Nov 20, 2020
Decision date	Apr 19, 2021
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Conformis, Inc.**
Location	Foster City, CA, US
Contact	Mary Kruitwagen
510(k) history	60 submissions · 60 cleared · 2005-2023